

SMART FACTORY
SMART QUALITY MANAGEMENT:
INDUSTRY 4.0 AND
QUALITY MANAGEMENT SYSTEMS

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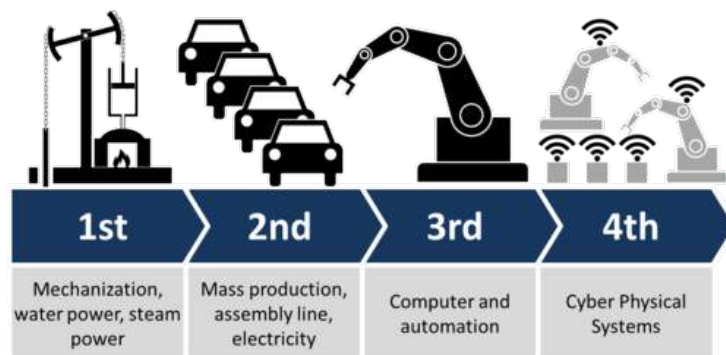
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1. A Quick Intro to Industry 4.0

INDUSTRY 4.0

Industry 4.0 is labeled as the fourth industrial revolution. Each of these revolutions has been triggered by technological innovation. The technical innovation that drove the 1st Industrial Revolution, at the end of the 18th century, was the introduction of water and steam-powered mechanical manufacturing. The 2nd Revolution was driven by electric-powered mass production and the division of labor. The continued automation of manufacturing through Information Technology and advancements in electronics inspired the 3rd Revolution.



Source: Christoph Rosser, allaboutlean.com

Industry 4.0 is more of a vision than a specific definition.

Industry 4.0 is more of a vision, than a specific definition, but it can be broadly defined as "the current trend toward automation and data exchange in manufacturing." The main concepts of Industry 4.0, based on the "Industrie 4.0 Working Group," are: the creation of the **Smart Factory**, **Cyber-Physical Systems (CPS)**, and the **Internet of Things (IoT)**.

A few of the technologies that will play a large role in Industry 4.0 are the Internet itself, Artificial Intelligence (AI), Machine Learning (ML), and Big Data Analytics. However, Industry 4.0 goes well beyond these three technologies. Data volumes have skyrocketed because of technological advances. Improved computational power, improved connectivity, new powerful wide area networks, and RFID have all contributed to this vast rise in data volumes. The list of technologies that are contributing to Industry 4.0 are rapidly expanding.

The Smart Factory

This is often what people mean when they talk about Industry 4.0. Also referred to as Connected enterprise, SMART manufacturing, and Manufacturing 4.0. A Smart Factory has intelligent, individualized products and processes. It is made up of products that know their manufacturing process as well as the consumer application, and therefore can self-direct their way through the supply chain. A Smart Factory is integrated and collaborative both vertically and horizontally in real time, within company boundaries and outside of traditional company boundaries.

Smart Factory integration and collaboration will expand outside of the organization to include traditional participants such as suppliers, but it will also include non-traditional participants such as the Internet of People (IoP) and the Internet of Services (IoS), and a whole host of applications that were previously inaccessible to smaller organizations. Pay-per-use people skills, services, and applications (in the Cloud) will become common place with Industry 4.0.

Cyber-Physical Systems (CPS)

Cyber-Physical Systems (CPS) are the key to Smart Factories as the CPS allows communication between humans as well as machines throughout large networks, often via the Internet of Things (IoT). CPS monitor physical processes, create a virtual representation of that physical world, and then make decentralized decisions. CPS are tightly integrated with the internet and its users; physical and software components are, for all intents and purposes, inseparable, and they interact with each other in a plethora of ways that change with the context of the current environment.

Internet of Things (IoT)

The IoT is the inter-networking of physical entities embedded with electronics, software, sensors, and network connectivity which enable them to collect and exchange data. The Industrial Internet of Things (IIoT) is simply the use of these things in manufacturing.

Market Drivers

The market drivers for Industry 4.0 are intense global competition, uncertainties in energy and supply costs, rising labor costs in many markets, consumer demand for higher quality at lower prices, the increased demand for customized products, decreasing product life cycles, and exponential growth in information technology. Manufacturing today, and even more so in the future, needs the ability to be more fluid, with the requirements for rapid product development and flexible production in complex environments.



Impact on Organization's Products & Processes

The emerging concepts and technologies of Industry 4.0 will change the way supply chains, factories, and people work. Products and processes will get smarter and more flexible. They are likely to be a part of a system where products, technology, services and people all interact to deliver more robust, higher-quality solutions to the market more quickly than ever before.

When contemplating the impact of Industry 4.0 on products and processes, let's consider the definition of a Smart Factory: it has intelligent products and processes. It is made up of products that know their manufacturing process as well as the consumer application, and because they are an integrated component of the CPS, they can self-direct their way through the supply chain. In a Harvard Business Review article by Michael Porter and James E. Heppelman, titled *How Smart, Connected Products are Transforming Competition*, the authors declare that, "smart, connected products ultimately can function with complete autonomy. Human operators merely monitor performance or watch over the fleet or system, rather than over individual units."

In medical device organizations, from a patient and post-market surveillance perspective, Smart Products will be able to combine the data they are receiving from the patient being monitored by the smart device, with data available from other patients with the same condition and device, and then recommend adjustments to improve device performance and, therefore, the well-being of the patient. This device learning will change the way treatment (not to mention diagnosis) is delivered to patients.

"Smart, connected products ultimately can function with complete autonomy."

Bottom Line: Industry 4.0 is the result of technological advancements. The benefit of applying those advancements is that it will enable industry to respond to the demands for individualized or personalized products, while simultaneously offering the benefits of mass production. This is typically coined as Mass Customization in a global market that grows more competitive and cost-conscious every day. Beyond the benefit of meeting the demand for individualized products, Industry 4.0 drives the opportunity for tremendous data-driven product and process improvements, increases in product quality, and more rapid communication throughout the demand chain.

2. Implications of Industry 4.0 for the Medical Device Industry

MEDICAL DEVICE INDUSTRY 4.0

Industry 4.0 is definitely going to require a technology upgrade in most companies, but that doesn't necessarily equate to a complete rip-and-replace of existing systems, if proper platform systems are in place. Most analysts, consulting firms, and work groups alike, agree that building an industry 4.0 roadmap will be key, and it will be transitional and incremental, executed over time. In the medical device industry, rapidly evolving technology will present a number of opportunities as well as challenges.



**Information Technology
and Operational
Technology need to
come together.**

A Focus on Digital Technologies

Initially investments will be focused on digital technologies. For many that will consist of modernization of existing equipment; for others it will require an investment in robotics, artificial intelligence, and 3D printers. For most, however, the focus will be on industrial control systems, sensors, connectivity devices, reliable data exchange utilities/tools, security, enterprise software platforms (ERP, MES or MOM, PLM, QMS, ASSET Management), pay-per-use software, IoT Platforms, and data analytics engines (more specifically, machine learning-based analytics). Information Technology and Operational Technology need to come together. The convergence of data from many different sources will drive the manufacturing supply chain in the Medical Device and Life Sciences industries, as it will in all industries.

Industry 4.0 and its use of both internal and external IoT data will dramatically increase the volume of data coming into the organization. The data needs to be transformed into information and predictive analytics that enable prevention as well as continuous improvement.

Data Security



With so much data coming from so many sources comes the question of data security (including securing patient data), data integrity, and IP protection. Ultimately, Smart Products will be able to accept and send data, so how do you ensure that incoming data isn't harmful to the device, and therefore the patient? How do you ensure that the information transmitted from the device provides what is needed, without exposing patient and IP information?

Data security will be one of the hurdles of Industry 4.0. Yet for Industry 4.0 to reach its full potential, information transparency is key, so digital trust is going to be imperative.

Investing in Change



Investment cannot simply be relegated to technology and equipment. There will need to be investments made in change management and employee training as well. Most people aren't comfortable with change, no matter how flexible they would like to be or how great the communicated benefit.

It will be critical to involve employees in the change process, training them along the way, as enhanced skill sets, which are new and different, will be required in the new Industry 4.0 paradigm. For Industry 4.0 initiatives to be successful, a cultural shift will be required. Corporate leadership will need to demonstrate and execute the new company strategy and cultural vision, one behavior at a time.

Bottom Line: The ultimate goal of all this technology is to create an industrial, digital ecosystem where products, man, machine, and Big Data interact through the organization's end-to-end value chain. There will be challenges, but the benefits to the organization and the patients they serve far outweigh the cost of transformation. In fact, in the PwC 2016 Global Industry 4.0 Survey titled [*Industry 4.0: Building the Digital Enterprise*](#), over half the respondents stated they expect their Industry 4.0 investments to yield a return within two years.

3. Impact on Validation, Regulatory and Quality Compliance

IMPACT ON VALIDATION

Validation will need to take on artificial intelligence and machine learning, and traditional validation methods are very likely to fall short here. As devices and software take in massive amounts of data, they learn and adjust. This learning comes from complex algorithms and methods that someone has programmed. As the system cross-references, correlates, and assimilates this data, it can recognize new patterns, store these patterns, and use them in future learning. These complex algorithms and methods can generate results that the programmer did not, or maybe could not, anticipate, and it can do it at record speeds!

According to [an article in Asian Scientist's August 15, 2016 issue](#), IBM's Watson was able to diagnose a rare form of leukemia in a patient in Japan in 10 minutes - a diagnosis that had eluded doctors for months. The doctors would have, through learning and process of elimination, come to the same diagnosis, however when treating disease, time is of the essence, and artificial intelligence surely sped up that process.

Consider now, an implantable device "learning" through data it has gathered from the patient, as well as from the IoT, regarding how to recalibrate itself for optimal patient performance. How do we validate that these self-learning, artificially intelligent systems are learning what they're supposed to? Machine Learning algorithms have not yet attained human learning capacity; learning that comes from experience, intuition, and the ability to integrate multiple contributing factors in decision making. Much investment in machine learning algorithms is needed before this level of learning will be readily available for medical devices. In the meantime, we need to consider what it is going to take to validate the AI and Machine Learning devices of the future.

The current validation thought is that we should always experience expected results, and our validation processes and techniques are geared towards the objective of demonstrating that we will always achieve expected results. In the Industry 4.0 future, we are very likely to experience unexpected results, and that should be expected. The power of AI and machine learning algorithms is that they do learn, and it will not be unusual for them to learn something that the originator of the algorithm didn't anticipate, and that learned result is valid even if it is unexpected.

"Smart, connected products ultimately can function with complete autonomy."



IMPACT ON REGULATORY COMPLIANCE

For the purposes of this ebook, we will focus on the FDA, as the possible regulatory impacts around the globe is a much longer discussion.

In July of 2016, the FDA issued guidance on three topics of great relevance to the future of medical device innovation.

General Wellness: Policy for Low Risk Devices; Guidance for Industry and Food and Drug Administration Staff

The 21st Century Cures Act amends the definition of a device to exclude certain software functions, therefore the guidance on General Wellness; Policy for Low Risk Devices is under review. The good news is that the FDA isn't going to regulate devices available via retail. These devices are for general wellness and are considered very low risk.

Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff

Real world evidence comes from data gathered outside of the clinical trial. The FDA may consider this data as valid scientific evidence, depending on the characteristics of that data. It is not changing the evidentiary standards used in regulatory decision making for initial approval; rather, it considers whether the device may be used for indications beyond the original approval. This is a start in paving the way for the use of outside data sources from the IoT.

Adaptive Designs for Medical Device Clinical Studies; Guidance for Industry and Food and Drug Administration Staff

This guidance speaks to the adaptive design of clinical trials. An adaptive design clinical trial allows for planned modifications to the clinical study based on the accumulation of study data without undermining the study's integrity and validity. Done properly, it will reduce the time and cost of going to market. When done poorly, it could put patients at risk unexpectedly.

The FDA is serious about doing the right thing. Protecting the patient is their primary focus, but they also want to credit medical device manufacturers that are doing the right thing and innovating as well.

In the *Wired* Article [Medicine is Going Digital and the FDA is Racing to Catch Up](#), Bakul Patel, Associate Center Director for Digital Health at the FDA, is quoted as saying, "We've been trying to translate the current regulation paradigm for digital. But what we have today, and what we're going to have tomorrow, are not really translatable. We need to take the blinders off, start with a clean sheet of paper."

Suffice it to say, the impact on regulations of Industry 4.0, and its deep utilization of AI and machine learning, is going to be significant.

IMPACT ON QUALITY COMPLIANCE

Industry 4.0 will surely have a major impact on Regulatory and Quality compliance, and thus the terms Quality 4.0 and EQMS 4.0 have evolved. One thing is certain: Quality leaders must harmonize, utilize, and share quality reports and analytics. Massive amounts of data will be available to Quality personnel in real-time, and from multiple sources simultaneously. That data must be used to enable quick, situational decision making.

Quality 4.0 is going to be a rapid-paced, self-directing environment. For Quality Management Systems and professionals to excel and contribute to bottom-line benefits to the organization, quality processes and data need to be an embedded, integral part of the ecosystem.

Understanding the Quality Impact of the Smart Factory

With Smart Products, Smart Processes, and Smart Machines, which can be self-directing and self-adjusting, Quality is going to need to determine what adjustments are allowed, without human intervention, and yet remain compliant with the organization's Quality policy. The same holds true for data coming back from in-use medical devices. If the device is making adjustments, Quality will need to define what adjustments can be made by the device on its own, without review and approval. In addition to determining the acceptable parameters for self-directing, self-adjusting machines, products, and processes, Quality will need to determine how to record that the changes occurred within those acceptable parameters.

Embed Quality throughout the Value Chain

Additionally, with integrated value chains there is the potential for last-minute changes from the customer that may need to flow quickly, if not directly, to the supplier. Traditionally, these changes might be seen as deviations at worst, or change orders at best. With the demand for more individualized products in the Industry 4.0 future, this will become a normal state. What does that mean for Quality? An organization's end-to-end processes need to include Quality throughout. Quality Management cannot function as the company historian, simply recording events. Quality Management will need to be integrated into core processes so that all departments are participating in, and responsible for, overall quality. Global Enterprise Quality Management Systems that are fully integrated into the Industry 4.0 ecosystem of the organization will be critical. Industry 4.0 processes will become much more collaborative, interactive, and responsive.

Embrace Data, Technology, and Innovation

Finally, Quality departments need to embrace data and technology and use them to drive innovation while improving overall quality. Technology can aid Quality Management's ability to monitor products and processes to prevent issues and downtime before they occur. Data inputs from multiple sources will improve product performance and fuel product innovation by providing engineering and development with continuous feedback and insight.

4. Focus on Quality

THE NEED FOR AUTOMATED, OPERATIONAL QUALITY RISK MANAGEMENT

The need for Operational Quality Risk Management doesn't start once Industry 4.0 comes along. It is needed today, as evidenced by the updates to standards such as ISO 13485:2016. Operational Quality Risk Management should be built into every QMS process you have. That said, Industry 4.0, and thus EQMS 4.0, are going to make embedding operational quality into risk processes that are outside of traditional QMS a must.

Let's consider again those intelligent products that can self-direct their way through the supply chain. Based on machine learning, the smart product directs itself down a path that is new. Should it be allowed, or should it be stopped? This decision needs to be made quickly as Industry 4.0 is a rapid-paced environment. By embedding operational Quality Risk into the decision process, not only can the determined route be sent to Quality, but to other teams required to review and approve the route, if review and approval is even required. It may be that the operational risk assessment shows the risk to be so low that the change proceeds without review and approval. The risk data (similarity/difference of equipment, similarity/difference of skill sets, capabilities assessments, etc.) can also be sent along with the overall risk rating.

Building operational quality risk into all organizational processes will improve operational efficiency as well as product quality. Operational efficiency is improved by alerting and routing for review and approval only those "items" that are of sufficient risk, as defined by the organization, to warrant review and approval. It will improve product quality by allowing AI and Machine Learning to do what they're intended to do: speed up the learning process and make appropriate decisions based on all that the smart product has learned.

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Quality 4.0 Investments to Support Industry 4.0

To make Quality and its contribution visible to the organization, investments are needed in the following areas:

- **Collaboration tools** to enable knowledge transfer across the enterprise;
- **Quality Intelligence tools (Analytics)** that serve not only as an alert system when something goes wrong, but as a predictive, and therefore preventive, tool;
- **IoT tooling** for the use of outside data to aid in the measurement of performance and effectiveness of not only the organization's product, but similar products sold by competitors;
- **Quality Management Platform with Integration Tooling.** So much of the compliance data that drives our current QMS paradigm is available from other systems, and this will be compounded in the future with Industry 4.0. As mentioned earlier, integration of enterprise QMS with the other enterprise applications of the organization (ERP, MES, PLM, etc.) is key in the Industry 4.0 enterprise, however, it is just as relevant today for compliance automation, process improvement, and product quality.

Investments by Quality in the above-mentioned areas will not only improve overall quality, but will make clear Quality's contribution to enhanced product quality and strategic organizational objectives .

How Quality Leaders Can Gain Organizational Support for the Technology Required for Industry 4.0/Quality 4.0



The traditional Quality model has been focused on compliance, which has contributed to the implementation of fragmented, non-harmonized processes. This, in turn, reduces Quality's ability to communicate and report to the organization lessons learned that will contribute to continuous improvement within the organization. Compliance is still required, however, it is not going to aid in Quality's ability to align with and participate in the organization's strategic goals and objectives.

For the above-mentioned reasons and many more, Quality is often seen as a cost center, and often an expensive cost center at that. By embracing and participating in the technologies, data, and other elements of Industry 4.0, medical device manufacturers can potentially reduce their total Cost of Quality (which includes the cost of good quality and the cost of poor quality) by 22-50%. This alone, however, is not enough to get leadership buy-in for the technology that Quality will need to invest in to keep up with Industry 4.0.

Strategic Objectives - Speak the Language of Business

Incorporating Quality into the organization's Industry 4.0 planning will provide increased flexibility, improved product quality, and reduced time to market.

To get approval to make these investments, Quality leaders must speak the language of business and be part of the dialog. That means speaking about how Quality improves the following metrics and improving them in alignment with the organization's strategic objectives.

- ▶ Improve operational efficiencies up to 50%
- ▶ Reduce costs up to 40%
- ▶ Increase revenue up to 40%
- ▶ Reduce non-conformance in manufacturing by up to 12%
- ▶ Improve Overall Equipment Effectiveness by up to 10%
- ▶ Improve product compliance by up to 4%
- ▶ Improve On-time deliveries by up to 2%
- ▶ Improve First Pass Yield up to 2%
- ▶ Reduce supplier defect rate up to 45%
- ▶ Increase successful new product introductions by up to 21%

Every organization's results will vary based on where they're starting from; therefore, it is best to start measuring today. Quality needs to demonstrate how incorporating Quality into the organization's Industry 4.0 planning, and making the Quality 4.0 investments discussed above, will result in increased flexibility, improved product quality, and reduced time to market. Most importantly, they should share how these investments will aid in meeting customer requirements by providing them with safe, effective products that improve the quality of their lives.



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